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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,310	08/31/1999	KOJI UKAI	425-736P	2449

2292 7590 03/27/2002

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/380,310	UKAI ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-10, 13-17 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoki et al (JP 07267850).

Aoki teaches a method of preventing the unpleasant taste of a medicine by providing a composition containing the medicine with the unpleasant taste, a water-soluble polymer and a waxy substance. The medicine can be any unpleasant pharmaceutical agent such as azelastine (an antiallergic agent), erythromycin and chloramphenicvol (antibiotics), Phenobarbital, diltiazem hydrochloride, etc (see pages 1 and 2 of translation).

Aoki teaches that the medicine constitutes from 1 to 50% by weight and the polymer constitutes from 5 to 60% by weight of the composition. Also Aoki teaches that the polymers are selected from the group consisting of cellulose, gelatin, carrageenan, casein, etc (see page 2, lines 12-16 and claim 5). The formulations can be in the form of granules, powder, dry syrup, tablets, etc (see abstract and claim 10).

Aoki teaches the method of preparing the composition which includes **mixing** of the medicinal component with the wax substance and the water-soluble polymer (see page 2, item 0013, claims 1 and 11).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4, 11, 18, 23 and 26 rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki in view of Matoba et al (5,464,612).

Aoki, discussed above, lacks specific teachings on preventing the unpleasant taste of donepazil hydrochloride.

Matoba teaches a solid preparation characterized by an effective mitigation of the bitterness or other unpleasant taste and/or odor of an active ingredient. The medicinally active ingredients having an unpleasant taste and/or odor may frequently have a basic group. The basic groups are such as a nitrogen-containing heterocyclic group such as piperidyl. Medicinally active agents having a bitter taste are such as antibiotics such as cefpodoxime, cerebral circulation improving agents, central nervous system drugs and psychotropic agents (col. 4, lines 1-63).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have substituted donepezil hydrochloride for other medicinal agents taught by Aoki, because donepezil hydrochloride, being a basic medication, has a bitter taste as taught by Matoba, and it would be a logical extension of the combined references to have included donepazil hydrochloride in a composition preventing the bitter taste, and because of widening the scope of medications treated to prevent their unpleasant taste.

Claims 5, 12, 19, 24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki et al in view of Drug Information on Vantin®, by Pharmacia /& Upjohn (obtained through on-line PDR).

Aoki, discussed above, teaching antibiotics, does not specifically disclose cefpodoxime.

Pharmacia /& Upjohn in the Drug Information on Vantin® disclose that the medication, also known as cefpodoxime proxetil, is available in both tablet form and powder for suspension. It discloses that each 5 ml of Vantin® oral suspension contains cefpodoxime proxetil equivalent to 50 mg or 100 mg of cefpodoxime activity after constitution and contains additives such as artificial flavorings, BHA, carrageenan, citric acid, etc (see page 2, lines 2-7).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have prepared the formulation of Aoki and substituted cefpodoxime proxetil for an antibiotic as taught by Pharmacia /& Upjohn with the reasonable expectations of obtaining a useful oral antibiotic therapy with no unpleasant taste for patients who need such therapy.

Response to Arguments

Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

Although applicant argues that Matoba, teaching the use of ion exchanger resin to prevent the bitter taste in medication formulations, it is the teachings of the type of the medication in need of such treatment that is used in combination with Aoki, and the method of making the composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
March 25, 2002

JOSE G. DEES
SUPERVISORY PATENT EXAMINER

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